

JAN 16 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:)	Docket No.:	4121-171
)		
Applicants:)	Conf. No.:	3755
)		
Application No.:)	Art Unit:	1645
)		
Date Filed:)	Examiner:	Maria Gomez
)		Leavitt
)		
Title:)	Customer No.:	
)		
DIAGNOSTIC CONJUGATE)		
USEFUL FOR)		
INTRACELLULAR IMAGING)		
AND FOR)		
DIFFERENTIATING)		
BETWEEN TUMOR- AND)		
NON-TUMOR CELLS)		

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FACSIMILE TRANSMISSION CERTIFICATE

ATTN: Examiner Maria Gomez Leavitt

Fax No. (571) 273-8300

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4

Number of Pages (including cover)

Kelly K. Reynolds

January 16, 2007

Date _____

**RESPONSE TO RESTRICTION REQUIREMENT IMPOSED IN DECEMBER 13, 2006
OFFICE ACTION IN U.S. PATENT APPLICATION NO. 10/502,442**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the December 13, 2006 Office Action in the above-identified application,

JAN 16 2007

4121-171

wherein a species restriction was imposed against previously pending claims 1-16 of the application, as set out below:

- I. c-myc-, c-ras-, henn-, sst1 or sst2-mRNA. Applicant is to choose one specifically named mRNA as recited in claim 7;
- II. Gd, Fe or F. Applicant is required to choose one specifically named diagnostic conjugate as recited in claim 9; and
- III. polylysine, polyglycine. Applicant is required to choose one specifically named spacer I and spacer II as recited in claim 12.

The requirement for a species election is traversed. As set forth in MPEP §803, a proper restriction requirement is made when the inventions are independent (MPEP §§ 802.01, 806.04, 808.01) or distinct as claimed (MPEP §§ 806.05-806.05(i)); and there is a serious burden on the Examiner if restriction is not required (MPEP §§ 803.02, 806.04(a)-(i), 808.01(a) and 808.02). However, even if the species are viewed as independent or distinct, but the claimed subject matter in each group is related by a "commonality of operation, function and effect" (MPEP § 806.04(e)), then requiring election of a single species is improper. Additionally, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

With regard to the species of Group I, the specifically named mRNAs, it is respectfully submitted that these mRNAs are related by a "commonality of operation, function and effect," as they are all capable of hybridizing with the antisense peptide nucleic acid (PNA) as described in claim 4, depending from claim 1 and further defining the address module (AS) of claim 1 as a PNA.

With regard to the species of Group III, the specifically named amino acids polylysine and polyglycine are not properly identified as a group. As can be seen in the specification at pages 6-7, the spacers are defined as follows:

"In a preferred embodiment, the transmembrane module (TPU) of the diagnostic conjugate is coupled to the address molecule (AS) via a covalently cleavable spacer I and/or the address module (AS) is coupled to the signaling module (SM) or a

4121-171

compound trapping the signaling module(SM) via a covalently non-cleavable spacer II.

"In a more preferred embodiment, spacer I comprises a redox cleavage site, e.g. a disulfide bridge (-cysteine-S-S-cysteine-O-N-H). the binding formed between the transmembrane module (TPU) and address module (AS) is a redox coupling (mild cell-immanent bond by means of DMSO; Reitsch and Beckwith, 1988, Ann. Rev. Gent 32: 163-184:

"Cysteine-SH SH-cysteine → cysteine-S-S-cysteine

...

"In an even more preferred embodiment, spacer II of the diagnostic conjugate is polylysine."

Therefore, spacer I and spacer II do not both comprise polylysine and/or polyglycine, but spacer I comprises polycysteine and spacer II comprises polylysine and the diagnostic conjugate, as set forth in the specification at pages 6-7 is coupled to spacer I and/or spacer II. Therefore choosing between polylysine and polyglycine is unnecessary, as these are separate parts of the same invention. Specifically, the conjugate of the invention can have a structure containing spacer I, spacer II or both spacer I and spacer II. Claim 14 of the invention recites a conjugate containing both spacers.

In order that this response fairly meets the substance of the Office Action in all respects, even though the species election requirement is traversed by Applicants as set forth above, a single disclosed species of each Group is hereby elected with reservation of the traversal:

- I. c-myc as specifically named mRNA as recited in Claim 7;
- II. Gd as specifically named diagnostic conjugate as recited in claim 9; and
- III. Polylysine as specifically named spacer as recited in claim 12.

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JAN 16 2007

In response to the Requirement for Restriction dated December 13, 2006, Applicants have provisionally elected, with traverse, c-myc of Group I, Gd of Group II and Polylysine of Group III.

Based on the foregoing, examination of the subject application is requested to commence on the basis of the elected species identified above.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

Respectfully submitted,

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